

Section 5 510(k) Summary

Submission Correspondent:	Oehm und Rehbein GmbH Contact: Franziska Günther Phone: (49) 381 36 600 500 Email: franziska.guenther@or-technology.com
Establishment Registration Number:	3006542593
Submission Sponsor:	Oehm und Rehbein GmbH Neptunallee 7c 18057 Rostock GERMANY Phone: (49) 381 36 600 500 Fax: (49) 381 36 600 555 NOV 05 2013
Date summary prepared:	1 October 2013
Device trade name:	dicomPACS®DX-R with flat panel
Device common name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Classification:	Class II
Product code:	MQB at 21 CFR Part 892.1650 LLZ at 21 CFR Part 892.2050
Predicate devices:	K083645 RadStar Digital Imaging System (5-Star Medical, Inc.) K102349 AeroDR System (Konica Minolta Medical & Graphic, Inc.)
Description of the device:	<p>The dicomPACS®DX-R with flat panel digital imaging system consists of two components, the dicomPACS®DX-R software for viewing captured images on a Windows based computer, and one of three solid state X-ray imaging devices: Toshiba FDX4343R, Toshiba FDX3543RP, or Konica Minolta AeroDR P-11 (1417HQ). The system will display high quality images in less than five seconds over a wide range of X-ray dose settings. The software has the following characteristics: The dicomPACS®DX-R software runs on an off-the shelf PC which forms the operator console. Images captured with the flat panel digital detector are communicated to the operator console via LAN or WLAN connection, depending on the model and the user's choice. dicomPACS®DX-R software uses the software API of the panel manufacturers to control the flat panels and to receive and to calibrate image data. The dicomPACS®DX-R software is an independent product for the acquisition, processing and optimisation of X-ray images (raw images) provided by flat panel (DR) systems or CR systems. In general, such software is also called „console software“ as it is installed on the so-called „console PC“ of the imaging device. dicomPACS®DX-R carries out the image processing of the raw images provided by the particular device and provides the radiographer / X-ray assistant with an optimum workflow for their work.</p>

Intended use of the device:	The <i>dicomPACS® DX-R</i> with flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.
Substantial equivalence to predicate devices:	All three receptor panels are identical in structure and share nearly identical Indications for Use. The included software offers the same functions as previously cleared in our software K091364. One flat panel of the proposed device is identical to that of the second predicate device. Apart from that, all panels share similar technical parameters as well as the same materials and conversion technique. <u>All panels have been previously cleared by FDA.</u>
Summary of Technological Characteristics	The three panels have the following specifications; Konica Minolta AeroDR Pixel Size 175µm, 1994 x 2430 Pixels. Toshiba FDX4343R, Pixel size 143µm, 3008(H)×3072(V) Pixels Toshiba FDX3543RP, Pixel size 143µm, 2448(H)×2984(V)
Summary of Findings from Non-Clinical Testing	Biocompatibility testing was conducted: In-vitro cytotoxicity, intracutaneous reactivity, and irritation/delayed type hypersensitivity. (Patient contact is rare and incidental). Electrical safety and EMC testing was conducted in compliance with IEC 60601-1 and IEC 60601-1-2. Software validation and risk analysis was conducted in compliance with FDA guidance documents. The suppliers of the respective panels performed MTF, DQE, linearity, and resolution measurements.
Summary of Findings from Review of Clinical Images	Images from all three panels were reviewed by a US Board Certified Radiologist. The panels produce images that are clinically acceptable. The images are of excellent quality, high resolution and are comparable to or better than the images from the predicate devices. A clinical study as described in the FDA Guidance Document Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices Document issued on: August 6, 1999 was conducted successfully.
Conclusion:	There are no significant differences between the <i>dicomPACS® DX-R</i> with flat panel digital imaging system and the predicate devices and therefore, <i>dicomPACS® DX-R</i> with flat panel does not raise any questions regarding safety and effectiveness. The <i>dicomPACS® DX-R</i> with flat panel, as designed, is as safe and effective as the predicate devices, and the device is determined to be substantially equivalent to the referenced predicate devices currently on the market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 5, 2013

Oehm Und Rehbein Gmbh
% Franziska Guenther
Assistant to the Management
Neptunallee 7c
Rostock, Mecklenburg-Vorpommern 18057
GERMANY

Re: K131211
Trade/Device Name: *dicomPACS® DX-R* with flat panel
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: Class II
Product Code: MQB
Dated: October 01, 2013
Received: October 03, 2013

Dear Franziska Guenther:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131211

Device Name
dicomPACS® DX-R with flat panel

Indications for Use (Describe)

The dicomPACS® DX-R with flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)